## Before the FEDERAL COMMUNICATIONS COMMISSION WASHINGTON, D.C. 20554

In the Matter of	
Investigation of the Spectrum Requirements for Advanced Medical Technologies	ET Docket No. 06-135
Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radio Communications Service at 401-402 and 405-406 MHz	RM-11271 ) )
DexCom, Inc. Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules	ET Docket No. 05-213
Biotronik, Inc. Request for Waiver of the Frequency Monitoring Requirements for the Medical Implant Communications Service Rules	ET Docket No. 03-92

## REPLY COMMENTS OF DEXCOM, INC.

DexCom, Inc. ("DexCom"), by its attorneys, hereby replies to comments filed in the above-captioned *Notice of Proposed Rulemaking* ("*NPRM*") and *Notice of Inquiry* ("*NOI*").<sup>1</sup> Virtually all of the relevant parties, including DexCom, urge the Commission to allow non-listen-before-transmit ("LBT") technology to operate on the main MICS band and to not fragment the MedRadio spectrum based on unnecessary technology distinctions. DexCom urges the Commission to adopt rules that permit operation of non-LBT technologies in the main MICS

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<sup>&</sup>lt;sup>1</sup> FCC 06-103 (rel. July 18, 2006).

band. DexCom also requests that the Commission not reduce the allowable power levels for non-LBT devices.

Additionally, no parties raised concerns that DexCom's technology, as it operates under the terms of the waiver, presents any risk of interference to LBT devices. For this reason, DexCom requests that the Commission either incorporate the terms of the waiver into its rules or grandfather DexCom's system into whatever new regulatory regime is adopted.

## **DISCUSSION**

In its comments, DexCom opposed any rule change that would create two tiers of medical devices, with devices that do not use LBT technology restricted to the proposed new 401-402 MHz and 405-406 MHz "wing" bands.<sup>2</sup> All but one medical device manufacturer, and both transceiver manufacturers, support this position. For example, AMIS and Biotronik support allowing non-LBT devices in the center of the band. And Boston Scientific terms the two-tiered approach "unnecessary and ill-advised," cautioning against an "overly narrow approach" and explaining that requiring different technical standards in the sidebands would suppress innovation.<sup>3</sup>

Moreover, most parties urge that the Commission strive for international harmonization of the MICS spectrum, both for the ease of patient travel and the cost-effectiveness of manufacturing MICS devices. As Timex explained,

<sup>&</sup>lt;sup>2</sup> Comments of DexCom, Inc. at 3.

<sup>&</sup>lt;sup>3</sup> Comments of Boston Scientific at 2-3.

"internationally compatible operations are a worthwhile goal as they will enable individuals to use these wireless products whether at home or overseas, and they also allow for lower-cost production as the same products can be sold in multiple countries." In sum, there is almost no support for bifurcating the MICS band.

DexCom demonstrated how a reduction in the MICS power levels would adversely affect its glucose monitoring devices by lowering the useful operating range of its short term sensor to less than two feet, rendering such critical medical technology effectively unusable by patients.<sup>5</sup>

Other parties share the concern that severely limiting power levels, as proposed in the NPRM, will cause operating ranges to be too short for useful transmissions. Boston Scientific requested that the Commission allow for even higher power levels in order to provide sufficient operating range for certain medical devices, noting, for example, that in an operating room devices that must operate outside of the sterile field would not have sufficient range to do so.6 DexCom would support increased power levels, and urges the Commission, at the very least, not to reduce the allowable power levels for non-LBT devices operating on the MICS channels.<sup>7</sup>

<sup>&</sup>lt;sup>4</sup> Comments of Timex Corp. at 1-2. *See also*, Comments of St. Jude (welcoming international harmonization); Comments of Boston Scientific at 6 ("it would useful to have an internationally harmonized band").

<sup>&</sup>lt;sup>5</sup> Comments of DexCom, Inc. at 3-4.

<sup>&</sup>lt;sup>6</sup> Comments of Boston Scientific at 9-10.

<sup>&</sup>lt;sup>7</sup> DexCom notes that a few parties provided questionable calculations, or relied upon incomplete assumptions, regarding what range could be achieved given certain power levels and duty cycles. *See, e.g.* Comments of Intel Corp. at Appendix 4. These parties

Finally, the Commission specifically sought comment on the propriety of extending the waiver granted to DexCom beyond the present waiver period of one year after the effective date of any new MedRadio rules adopted as a result of this proceeding.<sup>8</sup> Since no party commented, the Commission may assume that no one challenges the Commission's finding that the risk of interference from DexCom's devices, which transmit on a single frequency with a low duty cycle, is minuscule.<sup>9</sup>

As DexCom explained, it is able to operate under the terms of its waiver without risk of interference to other devices. <sup>10</sup> In fact, the interference analysis submitted by Biotronik indicates that the risk of interference even by LBT devices to other LBT devices is exceedingly low. <sup>11</sup> The risk of interference to a LBT device by a device operating at a 0.1 percent or lower duty cycle even would be less likely. Additionally, Boston Scientific explains that the present MICS frequency scan sensitivity levels are higher than necessary to prevent interference, and that LBT should not be mandated. <sup>12</sup> For these reasons, the FCC

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did not take into account many sources of signal loss, the most significant of which is antennae polarization. When signal loss is considered, the proposed power levels for the sidebands would not support the ranges suggested. AMIS, in its reply comment, states that it now has determined that 250 nW transmitted power is too low to ensure adequate robustness in communications on the sidebands. Reply Comments of AMIS at 1.

<sup>&</sup>lt;sup>8</sup> NPRM at para. 35.

<sup>&</sup>lt;sup>9</sup> Comments of DexCom, Inc. at 4-5 (noting that the Commission recognized in granting the waiver that DexCom's STS devices present a "virtually nil" probability of interference to other devices).

<sup>&</sup>lt;sup>10</sup> *Id*.

<sup>&</sup>lt;sup>11</sup> See e.g., Comments of Biotronik, Inc. at 6.

<sup>&</sup>lt;sup>12</sup> Comments of Boston Scientific at 11.

should allow DexCom to continue to provide its life-sustaining technology to people with diabetes for the indefinite future no matter what regulatory regime it adopts for MedRadio.

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Respectfully submitted,

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